

In the Claims:

1. (Original) A device for visualizing structure located on the interior of a visually opaque substance relative to a region of interest in a body, the device comprising:

a marker member, the marker member composed of a biologically stable material, the marker member capable of permitting non-obstructive visualization of at least one structure located relative to the region of interest, the marker member having an interior, a proximal end, and a distal end, the distal end of the marker member being removably insertable in the visually opaque substance in proximate relationship to a cavity of potential space defined therein;

an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the visually opaque substance when the marker member is in removable insertable position in the visually opaque substance; and

an imaging material contained relative to the marker member in a manner such that the imaging material does not directly contact the substance to be imaged, wherein the imaging material produces a signal detectable external to the visually opaque substance, the imaging material containing at least one radiopharmaceutical material, the radiopharmaceutical material producing an image detectable in at least one of positron emission tomography, and single photon emission computed tomography.

2. (Original) The device of claim 1 wherein the imaging material is dispersed in an essentially homogenous manner through at least a portion of the interior of the marker member.

3. (Original) The device of claim 2 wherein the imaging material is movably positionable at a discrete location relative to a longitudinal plane of the marker member.

4. (Original) The device of claim 3 wherein the marker member is a lumen.

5. (Original) The device of claim 4 further comprising means for movably positioning the imaging material relative to the lumen along the longitudinal plane of the lumen, the positioning means operable when the lumen is removably inserted in the visually opaque substance relative to the region of interest, the positioning means located adjacent the proximal end of the lumen.

6. (Original) The device of claim 4 wherein the lumen is composed of a biologically stable material capable of permitting a non-obstructive visual image in and during the procedures that detect and translate the detectable signal resulting from the imaging material, such that the detection signal is sufficiently perceptible on the exterior of the substance to be imaged, the signal instrumentally detectable.

7. (Original) The device of claim 6 wherein the biologically stable material is one which prevents significant contact between the imaging material integrated or contained in the lumen and the surrounding visually opaque material.

8. (Original) The device of claim 4 wherein the lumen is at least partially flexible.

9. (Original) The device of claim 8 further comprising:  
an interior lumen positioned coaxially interior to the flexible lumen at a defined interior diametric distance therefrom, the interior lumen defining a central inner cavity, wherein the interior and outer flexible lumen define a coaxial space therebetween, the imaging material contained external to the interior lumen.

10. (Original) The device of claim 9 further comprising means for temporarily inflating the interior lumen and the associated outer flexible lumen into deformable contact with the visually opaque substance, the inflating means located external to the visually opaque substance.

11. (Original) The device of claim 1 wherein the visually opaque substance in which the device is adapted to be removably inserted includes an anatomical structure having a preexisting cavity or potential space, the cavity of potential space including at least one of oral cavity, nasopharynx, oropharynx, larynx, esophagus, uterus, urethra, vagina, urinary tract, gastrointestinal tract, and stomach.

12. (Original) The device of claim 1 further comprising means for movably positioning the imaging material relative to the marker member along the longitudinal plane of the marker member, the positioning means operable when the marker member is removably inserted in the visually opaque substance.

13. (Original) The device of claim 12 wherein the marker member is composed of a biologically stable material capable of permitting a non-obstructive visual image in and during the procedures which detect and translate the detectable signal resulting from the imaging material, such that the detection signal is sufficiently readable on the exterior of the substance to be imaged, and the signal is instrumentally detectable.

14. (Original) The device of claim 13 wherein the biologically stable material is one which prevents significant contact between the imaging material integrated or contained in the marker member and the surrounding visually opaque material.

15. (Original) The device of claim 1 wherein the imaging material is distributed in a flexible substrate material, the flexible substrate material being biologically non-reactive, stable and movably positionable relative to the interior of the marker member.

16. (Original) The device of claim 15 wherein the flexible substrate containing the imaging material is a fluid selected from the group consisting of water, propylene, glycol, and mixtures thereof.

17. (Original) The device of claim 15 wherein the flexible substrate containing the imaging material is a flexible, biologically compatible organic material selected from the group consisting of thermosetting polymers, thermoplastic polymers, waxes, organic sols, organic gels and mixtures thereof.

18. (Original) The device of claim 1 wherein the marker member has an interiorly oriented surface and an opposed exteriorly oriented surface, and wherein the imaging material is in contact with the interiorly oriented surface.

19. (Original) The device of claim 18 wherein the imaging material is bonded to the interiorly oriented surface of the marker member.

20. (Original) A device for visualizing anatomical structure located in the interior of a visually opaque substance, the anatomical structure communicating with an external orifice, the device comprising:

a marker member, the marker member composed of a biologically stable material, the marker member having an interior, a proximal end, and a distal end, the distal end of the marker member adapted to be removably insertable in the anatomical structure defined in the visually opaque substance;

an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the visually opaque substance when the marker member is in removably insertable position in the anatomical structure in the visually opaque substance; and

an imaging material contained relative to the marker member in a manner such that the imaging material does not directly contact anatomical structure, the imaging material being a radiopharmaceutical compound having a radioisotope capable of producing a positron decay product, the imaging material producing a signal detectable external to the visually opaque substance wherein the decay product produced by the radiopharmaceutical compound produces products of an energy spectrum of varying wavelengths including at least one of photons, electrons, annihilation photons and positrons, said products detectable by detection devices external to the visually opaque substance, the decay product detectable by at least one of positron emission tomography detectors and single photon emission computed tomography detectors.

21. (Currently Amended) The device of claim 20 wherein the detectible decay ~~produce~~ product is generated by positron emission events and is detectable in a range between about 0.01 and about 2 cm.

22. (Original) The device of claim 20 wherein the anatomical structure visualized is at least one of oral cavity, nasopharynx, oropharynx, larynx, esophagus, rectum, uterus, urethra, vagina, urinary tract, and gastrointestinal tract.

23. (Original) The device of claim 22 wherein the radiopharmaceutical material produces a detectable gamma particle emission in a range between about 30 KeV and about 1000 KeV.

24. (Original) The device of claim 20 wherein the imaging material further comprises a CT contrast agent.

25. (Original) The device of claim 24 wherein the CT contrast agent is selected from the group consisting of iohexol, diatrizoate sodium, and mixtures thereof.

26. (Original) The device of claim 20 wherein the imaging material is an MRI contrast agent.

27. (Original) The device of claim 26 wherein the MRI contrast agent is selected from the group consisting of gadopentate dimeglumine, gadolinium compounds, vitamin E containing compounds, and mixtures thereof.

28. (Currently Amended) A device for visualizing anatomical structures located on the interior of a biological system, the device comprising:

a marker member, the marker member composed of a biologically stable material capable of permitting non-obstructive visualization of an anatomical structure of interest, the marker member having a proximal end, a distal end opposed to the proximal end, the distal end removably insertable in a suitable cavity defined as an anatomical structure in the biological system;

an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the

marker member to a location external to the biological system when the marker member is in removable insertable position in the biological system; and

an imaging material contained relative to the marker member such that the imaging material does not directly contact the biological system, the imaging material producing a signal detectable external to the biological system and comprising at least one radiopharmaceutical material, the radiopharmaceutical material producing at least one decay product including at least one of photons, electrons, annihilation ~~photos~~ photons, and positrons, said product detectable by detection devices external to the biological system, the detectable product detectable by at least one of positron emission tomography detectors, and single photon emission computed tomography detectors; and

means for movably positioning the imaging material while the marker member is in position in the biological system.

29. (Original) The device of claim 28 wherein the marker member is composed of a biologically stable material capable of permitting a non-obstructive visual image in and during imaging procedures which detect and translate the detectable signal resulting from the imaging material, such that the detection signal is sufficiently readable on the exterior of the substance to be imaged, and the signal is instrumentally detectable.

30. (Currently Amended) The device of claim 29 wherein the imaging material is selected from the group consisting of:

- a. MRI contrast agents selected from the group consisting of paramagnetic compounds, and supermagnetic compounds;
- b. CT contrast agents selected from the group consisting of iohexol, diatrizoate sodium, and mixtures thereof; and
- c. Ultrasound imaging materials; and mixtures thereof.

*[extra spaces removed from Claim 30]*

31. (Original) The device of claim 30 wherein the imaging material is dispersed in an essentially homogenous manner through at least a portion of the interior of the marker member.

32. (Original) The device of claim 29 wherein the biologically stable material of the marker member is one which prevents significant contact between the imaging material integrated or contained in the marker member and the surrounding biological system.

33. (Original) The device of claim 28 wherein the marker member has at least one hollow chamber defined therein, the hollow chamber adapted to contain the imaging material for at least an interval sufficient to obtain images of the structure to be analyzed.

34. (Original) The device of claim 33 wherein the marker member comprises at least one lumen.

35. (Original) The device of claim 34 wherein the lumen is at least partially flexible and the marker member further comprising:

an interior lumen positioned coaxially interiorly to the flexible lumen at a defined diametric distance therefrom, the interior lumen defining a central interior cavity, wherein at least one imaging material is positioned at a location in the marker member.

36. (Original) The device of claim 35 wherein the imaging material is positioned at a location between the interior lumen and the interior surface of the outwardly positioned lumen.

37. (Currently Amended) The device of claim 35 further comprising:

a second imaging material distinct from the imaging material contained between the flexible lumen and the interior lumen, the second imaging material contained in the central interior cavity in the interior lumen, wherein at least one of the imaging material and the second imaging material produces the signal detectable external to the biological system.

38. (Original) The device of claim 37 further comprising means for temporarily inflating the interior and flexible lumen into conforming contour with the cavity in the biological system.

39. (Original) A method for visualizing structure in a body, the method comprising the step of:

registering a first image with a second image, wherein the first image is derived from at least one of PET and SPECT, and the second image is derived from at least one of MRI, CT, PET, SPECT, and ultrasound, wherein the first and second images include at least one region of interest elucidated by a device removably inserted in the body, the removably inserted device including a marker member composed of a biologically stable material,

wherein the marker member includes:

- a. an interior, a proximal end, and a distal end, the distal end of the marker member being removably insertable in the body in proximate relationship to a cavity or potential space defined therein;
- b. an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the body when the marker member is in a removably inserted position in the body; and
- c. imaging material contained relative to the marker member in a manner such that the imaging material does not directly contact the substance to be imaged, wherein the imaging material produces a signal detectable external to the body.

40. (Original) The method of claim 39 wherein the marker member is associated with at least one critical structure.

41. (Original) The method of claim 39 wherein the registration step comprises registration of at least two sequential images.

42. (Original) The method of claim 39 further comprising the step of verifying image registration.

43. (Original) The method of claim 42 wherein image registration verification includes at least one of point fiducial matching and landmark-based image registration.



44. (Original) The method of claim 42 wherein the image registration verification step comprises application of at least one mutual information-based automatic registration algorithm.

45. (Original) The method of claim 39 wherein the first image is derived from PET and the imaging material has at least one first radionuclide and wherein the second image is derived from PET and the imaging material has at least one second radionuclide, wherein the second radionuclide is different from the first radionuclide.

46. (Original) The method of claim 39 wherein the registration step further comprises alignment of at least two intra-subject, intra-modality images.

47. (Original) The method of claim 39 wherein the registration step further comprises at least two intra-subject, inter-modality images.

48. (Original) The method of claim 39 wherein the registration step further comprises at least two inter-subject, inter-modality images.